REMARKS

Claims 1, 2 and 4 are currently pending in this application. Claim 1 has been amended to delete recitation of the reservoir being made of synthetic plastic and include recitation of "the lactose monohydrate being characterized by a solution enthalpy of ≥ 50 J/g" and "wherein the excipient is not a mixture of excipients obtained by mixing together excipient fractions with different average particle sizes." Support for these amendments are found, e.g., in the specification on page 6, lines 26-28, and page 7, lines 11-14. Claims 4 and 12 have been cancelled. Applicants reserve the right to pursue cancelled subject matter in a continuing application claiming priority herefrom under 35 U.S.C. §§ 120 or 121. No new matter is presented by way of this amendment.

Rejection under 35 U.S.C. § 103:

Claims 1, 2 and 4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 02/36163 in view of U.S. Patent No. 6,623,760. Applicants respectfully traverse.

As an initial matter, the Examiner points to a description on aerosols in WO 02/36163 (English-language equivalent CA 2436537, submitted herewith in an Information Disclosure Statement), whereas the claims being examined in the present application are directed to inhalable powders. Applicants also point out that the section in WO 02/36163 relating to an inhalable powder of two active substances is found on pages 8 and 9 of the English-language equivalent, CA 2436537.

Applicants have amended claim 1 to more particularly point out the subject matter being claimed. For example, the limitation *"wherein the excipient is not a mixture of excipients obtained by mixing together excipient fractions with different average particle sizes"* is based on the description on page 6, lines 26-28. Furthermore page 4, line 24-28 of the description provides that the "10% fine content in this instance refers to the 10% value of the volume distribution measured using laser diffractometer. In other words, for the purposes of the present invention, the 10% fine content denotes the particle size below which 10% of the quantity of particles is found (based on the volume

distribution)." This term does not therefore refer to a percentage of a separately added finer excipient fraction. Instead, the current application discloses an excipient for use with the invention which is not a mixture of excipient fractions with different average particle sizes. WO 02/36163 is just the opposite in that finer excipient fractions may be added:

> It may sometimes seem appropriate to add finer excipient fractions with an average particle size of 1 to 9 μm to the excipients mentioned above. See, page 8, lines 19-21, of CA 2436537, emphasis added.

In addition to this distinction, the Examiner also acknowledges that there is no mention of fine particle content in WO 02/36163.

To supply the missing element of fine particle content (or desired particle distribution), the Examiner relies on US 6,623,760. This reliance is misplaced however for at least two reasons. First, the '760 patent discloses "*[p]articles of solid carrier in accordance with the present invention [US 6,623,760], preferably will be produced such that they have a pre-determined convertible amorphous content ranging from between 1 to about 20 J/g and a particle size distribution of at least 60% by volume less than or equal to 5 μm. ... Most preferably, the particles of solid carrier will have a pre-determined convertible amorphous content ranging from between 3.8 to about 7 Joules/gram and a particle size distribution of at least 80% by volume less than or equal to 5 μm.*" Given that 60% or 80% of the particles are less than 5μm, that means that the average particle size of the solid carrier disclosed in '760 patent will most likely be around or below 5 μm and not between 10 and 50 μm as in the present invention.

Secondly, the solid carrier disclosed in '760 patent is characterized by a specific amorphous content, wherein the crystallization enthalpy has to be in the range of about 1 to about 20 J/g. In contrast, the excipients used in the present invention are characterized by high crystallinity (page 7, lines 9-10, of the specification). When the excipient is lactose monohydrate, for example, the crystallinity of lactose assessed by means of solution enthalpy should be preferably $\geq$ 50 J/g (page 7, lines 11-14, of the specification). The current claims have been amended to specifically point out this feature, which is not disclosed by the '760 or the WO 02/36163 and which could not be contemplated by one of skill in the art reading these disclosures.

In summary, the combination of WO 02/36163 and US 6,623,760 does not render the instant application obvious because both references either independently or together teach away from the present invention in the aspects described above. Applicants respectfully request withdrawal of this rejection.

Rejection under 35 U.S.C. § 103:

Claims 1, 2, 4 and 12 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that the previous claim amendments "refer to delivery from a material made from a synthetic polymer, however the specification clearly states that the reservoir is made from this material. Clarification is required in the claims." In response, applicants delete recitation of the previously added terms, mooting this rejection.

Applicants respectfully submit that all the pending claims are allowable. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Respectfully submitted,

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